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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,997	06/23/2000	IMRE KOVESDI	204526	8984

23460 7590 03/12/2004

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,997

Applicant(s)

KOVESDI ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,11-14 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,11-14,18-21 and 24-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's amendment and/or response to the previous Action.

***Election/Restrictions***

Claims 22-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 6/24/03.

This application contains claims 22-23 drawn to an invention nonelected with traverse in the paper filed 6/24/03. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Specification***

The amendment to the specification at page 8, line 1, filed 12/16/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states

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that no amendment shall introduce new matter into the disclosure of the invention.

In the response filed 12/16/03, the applicant indicates that the specification has been amended to include text from U.S. Patent No. 5,851,806, incorporated by reference in the instant specification. However, the applicant did not file an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. Also, the first sentence that is incorporated, "The present inventive adenoviral vector ..." constitutes new matter because by amending the instant application to include this sentence, it makes it improperly appear that the present inventive adenoviral vector being referred to is the one in the instant application, when it actually refers to the inventive adenoviral vector of U.S. Patent No. 5,851,806, which is quite different.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

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use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8, 11-14, 18-21, and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the response filed 12/16/03, the applicant amended claim 1 to read on a replication deficient adenoviral vector comprising an adenovirus serotype 5 genome and comprising ...

- (b) the adenoviral vector is rendered replication deficient by deletion of all of the E1 region and all of the E4 region and
- (c) the adenoviral vector comprises a pGUS spacer sequence in the E4 region, wherein the pGUS spacer comprises an SV40 polyadenylation sequence.

The applicant also indicated that the support for the amendment came, from among different places in the specification, and by the text of U.S. Patent No. 5,851,806. However, these sections do not provide support for the claims as amended because nowhere does the specification provide support for an adenovirus being deleted of all of the E4 region, wherein the adenovirus comprises a pGUS spacer in the E4 region. The

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amended section begins "The present inventive adenoviral vector ...". This refers to the adenoviral vectors of the patent, not of the instant application. Parts of the vectors taught in the patent cannot be directly combined in any combination with the rest of the specification because there is no support for mixing and matching components of the vectors taught by the patent with the components taught in the instant specification. The adenoviral vectors referred to within the patent stand alone as their own constructs because that is how the references are recited in the specification. The section of the patent added by amendment teaches the pGUS spacer in a region deficient for E4, not an E4 region that is completely deleted. There is no support for the combination as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 11-14, 18-21, and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the use of "deletion of all of the E1 region and all of the E4 region, and (c) the adenoviral vector comprises a pGUS spacer sequence in the E4 region" renders the claims vague and indefinite because it is unclear how both limitations can be present, that all of the E4 region is deleted and that the adenoviral vector comprises a pGUS spacer sequence in the E4 region. Since all of the E4 region is deleted, then there is no E4 region for the pGUS spacer to be present in. It should be noted that no potential art rejection could be made because of the vague and indefinite nature of what is now being claimed.

#### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

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is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be



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responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



*Terry A. McKelvey*

Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

March 8, 2004